

PATENT COOPERATION TREATY

PCT

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 100643-1 WO	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE 2003/000371	International filing date (day/month/year) 03.03.2003	Priority date (day/month/year) 04.03.2002
International Patent Classification (IPC) or national classification and IPC A61K 9/72, A61K 9/14, A61K 47/26		
Applicant AstraZeneca AB et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

Date of submission of the demand 15.09.2003	Date of completion of this report 13.05.2004
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Solveig Gustavsson/BS Telephone No. +46 8 782 25 00

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE 2003/000371

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished

- ☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

- ☐ the claims:

pages _____ as originally filed/furnished

pages* _____ as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

- ☐ the drawings:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE 2003/000371

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-9</u>	YES
	Claims	<u></u>	NO
Inventive step (IS)	Claims	<u></u>	YES
	Claims	<u>1-9</u>	NO
Industrial applicability (IA)	Claims	<u>1-9</u>	YES
	Claims	<u></u>	NO

2. Citations and explanations (Rule 70.7)

The opinion is based on the results of the international search report. The following documents were considered relevant:

- A. US5709884
- B. US5747445
- C. WO9831351
- D. WO9831353
- E. US6027714
- F. EP1238661
- G. US6004574

Document A pertains to a process for providing a stable crystalline form to a fine-grained substance. The substance has the aerodynamic properties required for inhalation. Suitable carriers include maltitol, and active substances mentioned are well-known beta-adrenergic agonists and anti-inflammatory glucocorticoids. See column 3, lines 45-57 and column 3 line 60-column 4 line 36.

Document B concerns a powder preparation for inhalation. Insulin is the active substance used. Non-reducing sugars (e.g. maltitol) are the preferred carriers. See column 8 lines 40-48 and claim 22.

In document C a composition comprising formoterol and a carrier substance chosen among mono- di- or polysaccharides, sugar alcohols or other polyols, e.g. maltitol, is shown. See page 2 lines 9-12.

From document D a composition comprising terbutaline sulphate and a carrier substance is known. The carrier is e.g.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: V

maltitol. See page 1 line 29-page 2 line 2.

Document E concerns a dry powder composition that contains budesonide and a carrier substance. The carrier is selected from lactose, glucose, raffinose, melezitose, lactitol, maltitol, trehalose, sucrose, mannitol and starch. See column 1 lines 34-39 and claim 9.

Document F shows different carrier materials for dry powder inhalators. Among the carriers tested, maltitol (Amalty) is included. See examples 1-2.

Document G is considered to represent prior art and will not be further addressed.

Thus, in documents A-F non-reducing sugars are suggested as carriers in powders for inhalation. Maltitol is mentioned in all documents A-F. Therefore, a person skilled in the art who is posed with the problem of finding a suitable carrier for use in inhalation compositions, would try the carriers suggested in documents A-F and would select maltitol, since it is a substance with properties that are suitable for use in inhalation compositions.

Therefore, claims 1-9 lack the requirement of inventive step.